REMARKS AND ARGUMENTS

Claims 1-2, 5, 7-18, 21-23 are pending with the entry of this Amendment. Claim 1 has been amended to better claim the subject matter which Applicants regard as the invention. Specifically, amended claim 1 incorporates the particle size, limitation of claim 4 and to exclude compositions containing cholera toxin or cholera toxoid. Similarly, amended claim 18 incorporates the particle size, limitation of claim 19 and to exclude compositions containing cholera toxin or cholera toxoid. Claims 3, 4, 6, and 19-20 have been canceled without prejudice. Claims 2, 5, 7-16 and 21 have been amended for improved clarity for which support can be found throughout the Specification. None of the amendments made herein constitute the addition of new matter. The amendments presented herein simplify the issues for appeal and/or place this case in condition for allowance.

The Rejection under 35 U.S.C § 103:

Claims 1-23 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Glenn *et al.* (U.S. Patent No. 5,980,898). Applicants respectfully traverse this rejection.

Without acquiescing to this aspect of the rejection, claims have been amended to define the invention more specifically and distinctly. For example, amended claim 1 specifically recites that the antigen is of particulate nature, and a defined size, i.e., about 50 to 200 nm in diameter, and the immune composition does not contain cholera toxin or cholera toxoid protein. Amended claim 1 is fully supported by the as-filed Specification, from page 4, line 21 to page 5, line 13, lines 1-8 of page 6, Example 2 on page 10, and the as-filed claims 1 and 4.

Applicants submit that the claimed invention as amended is not *prima facie* obvious over Glenn *et al.* The claimed invention is distinct from that of Glenn *et al.* in two major aspects; 1) the use of particulate antigens of certain size to induce an immune response is taught herein whereas **soluble** proteins as antigens were used in Glenn *et al.*, as evidenced in the Examples

but the antigens overlap

not necessarily

disclosed, and 2) the claimed method does not use cholera toxin or cholera toxoid protein as an adjuvant whereas Glenn *et al.*'s system uses an antigen and cholera toxin as an adjuvant to induce an immune response. There is no teaching or suggestion in Glenn *et al.* to motivate a person of ordinary skill in the art to make the invention as claimed, i.e., a method for inducing an immune response using the particulate antigens of about 50-200 nm in diameter without the aid of cholera toxin or cholera toxoid protein.

The Office Action states:

> 1) Glenn *et al.* (U.S. Patent No. 5,980,898) teaches a transcutaneous immunization formulation comprising antigen and an adjuvant applied to unbroken skin and without perforation of the skin induces an immune response, see abstract particularly, 2) Glenn *et al.* further teaches that the antigen may be derived from a virus, see col. 3, lines 64-66, and 3) Among the viruses that can be used in the practice of the invention Glenn teaches hepatitis, influenza, measles and vaccinia. See particularly column 9, lines 13-24.

With respect to the first allegation, Applicants point out that, with the entry of the present Amendment, the amended claims specifically recite that the use of particulate antigens of diameter about 50-200 nm without cholera toxin or cholera toxoid protein in a method for inducing an immune response. Thus, the claimed invention is not taught or suggested by the abstract of Glenn *et al.*

With respect to the second allegation, which is based on the statement, "The antigen may be derived from a pathogen that can infect the organism (e.g., bacterium, virus, fungus, or parasite)...." (column 3, lines 64-66), Applicants submit that this statement was made in the context to indicate that an antigen can be derived from a pathogenic organism such as virus, (e.g., viral coat protein) for use in the method of Glenn *et al.* There is nothing in the quoted

passage that would teach or suggest to a person of ordinary skill in the art that relatively large particulate antigens without the use of cholera toxin or cholera toxoid protein would be effective in inducing an immune response.

The third allegation is based on the statement, "Viruses include, for example: adenovirus...hepatitis...influenza, measles and vaccinia..." (column 9, lines 13-24). Applicants argue that the statement was made in the context to provide a list of infectious pathogens against which the antigens (i.e. soluble proteins) can be used for vaccination, not as the antigens, as taught in the present application. This is evident in the two preceding paragraphs (from column 8, line 66 to column 9, line 12).

The present claimed invention is a method for inducing an immune response using a composition comprising a large, particulate antigen (e.g., a virus or a virus-like particle) of 50-200 nm in diameter without the aid of cholera toxin or cholera toxoid protein, which is administered through the unbroken skin. The inventors were the first to discover this method. When this discovery was made, it was not expected in the art that a large particulate antigen without an adjuvant would induce an efficient immune response when administered onto the unbroken skin, as demonstrated in the present application. The claimed invention is not taught or suggested by Glenn *et al.*, particularly the quoted passages. Glenn *et al.*, at best, provides mere speculation without presenting any actual data. The Examiner has not yet specifically identified the principle, known to one of ordinary skill, which suggests the claimed invention based on the cited reference. See *In re* Lee 61, U.S.P.Q.2d, 1430 (Fed. Cir. 2002).

In summary, based on the foregoing amendments and arguments, it is submitted that the amended claims are not *prima facie* obvious over Glenn *et al.* Withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

Conclusion

Based on the foregoing, this case is deemed to be in condition for allowance and passage to issuance is respectfully requested.

It is believed that no additional fee is required for this submission. However, if the amount submitted is incorrect, please charge any deficiency or credit any overpayment due under 37 C.F.R. 1.16-1.17 to Deposit Account No. 07-1969.

Respectfully submitted,

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